

R E M A R K S

A. Status of the Application

Claims 1-41 are pending in this Application. Pursuant to a restriction requirement, the Examiner has withdrawn from consideration claims 4-8, and 26-30. Claims 1-3, 9-25 and 31-41 stand rejected. Applicants respectfully traverse these rejections and request a reconsideration of the same in view of the Amendments and Remarks contained herein.

B. Election/Restriction

The Examiner has issued an Election/Restriction requirement requiring Applicants to select for immediate prosecution Species I directed to a copolymer of ethylene and propylene or Species II-to-a blend of two propylene-containing copolymers. Applicants confirm that it has elected Species I for prosecution with traverse. Applicants acknowledge the Examiner's statement that polymer blends containing one ethylene and propylene copolymer is patentably distinct from a blend containing two propylene containing polymers. However, pursuant to M.P.E.P. § 803, a restriction requirement is proper only if: (1) the inventions are independent or distinct as claimed, and (2) there would be a serious burden on the Examiner if the restriction is not required. Applicants respectfully submit that a search and examination of the claims covering Species I and II would not impose a serious burden on the Examiner. Accordingly, Applicants request a withdrawal of this requirement. Applicants provisionally elect to prosecute claims 1-3, 9-25 and 31-41.

C. Information Disclosure Statement

In paragraph 9 of the Office Action, the Examiner noted that copies of several cited U.S. Patents were not included in the IDS submitted on October 2, 2000 (Paper No. 3), and as such these references were not considered by the Examiner. Applicants enclose herewith copies of the missing U.S. Patent documents, and respectfully request the Examiner's consideration of these documents.

The Examiner also noted that two non-US citations were not considered because no English translation or statements regarding relevance were provided. Applicants are in the

process of obtaining said translations, and will submit them to the Examiner for his consideration upon Applicants' receipt of same.

D. Rejections under 35 U.S.C. 112

The Examiner rejected claims 2, 9-15, 24, and 31-37 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner states that the claims are not clear on whether they require or do not require the recited components. Applicants have amended the claims to clarify. It is clear both claim 1 and claim 21 each require at least two components. Applicants submit this amendment overcomes this rejection and request a withdrawal of all of the rejections made under 35 U.S.C. §112.

E. Rejections under 35 U.S.C. 103 (a)

The Examiner rejected claims 1-3, 16, and 21-25 under 35 U.S.C. §103(a) as being unpatentable over Aoyagi et al. (US 4,453,940) in view of Chundury et al. (US 5,601,889), claims 17-20 and 38-41 under 35 U.S.C. §103(a) in further view of Barney et al. (US 6,203,535 B1), and claim 23 under 35 U.S.C. §103(a) in further view of Occhiello et al. (EPO 0423499A2).

1. Aoyagi et al. In View of Chundury et al. Does Not Render the Present Invention Obvious.

Claims 1-3, 16 and 21-25 stand rejected under 35 U.S.C. §103(a) as unpatentable in light of Aoyagi et al. in view of Chundury et al. Applicants respectfully traverse these rejections and request a withdrawal of the same.

Aoyagi discloses fabricating medical utensils including medical containers from particular copolymers. The copolymers include EVA. Aoyagi discloses subjecting the copolymer to gamma or electron beam radiation to provide a cross-linking of from 20 to 75% using dosage amounts from 1 to 10 Mrad (10-100 kGys). (Col. 4, lines 45-54).

Chundury discloses fabricating radio frequency weldable articles from polymer blends of: (A) at least one ethylene vinyl acetate copolymer in an amount greater than 55% of the blend (or the balance of the blend), (B) at least one propylene ethylene copolymer in an amount from about 15% to about 60%, and (C) (1) from about 0.01% to about 5% by weight of a cross-linking

agent, (2) from about 0.1% to about 35% by weight of one or more polymers selected from: (i) at least one co-, or terpolymer of at least one vinyl aromatic compound; (ii) at least one co-, or terpolymer of an alpha-olefin, and at least one monomer selected from the group consisting of an acrylic acid, an acrylic ester, a vinyl silane, and a vinyl alcohol; (iii) at least one polyolefin other than a propylene homopolymer or a propylene-ethylene copolymer; (iv) at least one polyetheramide block copolymer; (v) at least one ionomer; (vi) at least one oxidized polyolefin wax, or mixtures of (1) and (2). The polymer blend are cross-linked using chemical cross-linking agents or by using other free radical generators including electron beams and gamma rays. (Col. 4, lines 42-58).

To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be a suggestion or motivation to modify the prior art reference, (2) the prior art reference must teach or suggest all of the claim limitations of the claimed invention, and (3) there must be a reasonable expectation of success. See In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants submit that none of the foregoing three criteria have been satisfied.

There is no motivation to combine the references. Aoyagi discloses preparing medical containers from a copolymer having a specified formula. There is no disclosure in Aoyagi of utilizing a blend of more than one polymer to achieve its goal. Chundury discloses utilizing multiple component polymer blends including EVA as a required component. Accordingly, Aoyagi's disclosure of utilizing a single resin to satisfy its goal teaches away from utilizing a multiple component blend.

The Examiner's citation to Chundury at col. 2, lines 49-54 would not motivate one of ordinary skill in the art to substitute the polymer blends of Chundury with the use of a single copolymer of Aoyagi. The Examiner states that Chundury emphasizes the use of non-halogen containing polymers for environmental concerns. Aoyagi discloses numerous copolymers that are suitable for fabricating an autoclavable medical fluids container. Some of the copolymers include halogens while others do not. One of ordinary skill in the art may be motivated away from utilizing the halogen-containing copolymers of Aoyagi but is unlikely to be motivated to implement the blends of Chundury in place of the use of a single copolymer of Aoyagi. Accordingly, there is no motivation within these references to substitute the polymer blends of Chundury with the use of a single copolymer taught by Aoyagi.

Second, the combination of Aoyagi and Chundury do not teach all of the limitations of claims 1 and 21. Claims 1 and 21 recite a flowable materials container from a polymer blend containing at least two components. The first component is selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, (2) ethylene copolymerized with lower alkyl acrylates, (3) ethylene copolymerized with lower alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend. The second component is selected from (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers. The second component is present in an amount from about 45% to about 1% by weight of the blend. Claim 1 further recites a list of material properties of a film made from the recited blend. Claim 21 further recites a film made from the blend is subjected to electron beam radiation having an energy from 150 Kev to 10Mev to provide a dosage amount from about 20 kGy to about 200 kGys.

If the blends of Chundury were substituted for the single copolymer of Aoyagi one would have a polymer blend of EVA, PP from 15% to about 60% with at least one additional polymeric component from 0.1 to 35% by weight of the blend. The additional polymer components can be selected from a group including, among others, a copolymer or terpolymer of an alpha-olefin and at least one monomer selected from acrylic acid, an acrylic ester a vinyl silane or a vinyl alcohol. Chundury does not disclose utilizing from about 55% to about 99% of (1) an ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, (2) ethylene copolymerized with lower alkyl acrylates, (3) ethylene copolymerized with lower alkyl substituted alkyl acrylates and (4) ionomers. Chundury's disclosure of utilizing EVA does not meet any of these recited polymers. Chundury discloses using as a third polymer including alpha-olefins and acrylic acid groups but only up to 35% by weight and not the recited weight percentages of from about 99% to about 55%. Thus, even if the Chundury blends were substituted for the single copolymer of Aoyagi all limitations of claims 1 and 21 would not be present.

Third, there is no reasonable expectation of success. Aoyagi specifies for its single polymeric component suitable cross-linking is achieved by applying electron beam voltages of 2 Mev for a dosage of from 1-10 Mrad (10-100 kGys). (Col. 4, lines 44-54). Chundury discloses

that electron beams can be used as a free radical generator. (Col. 4, lines 57-58). However, Chundury does not disclose what electron beam voltages and dosages are required to achieve satisfactory cross-linking. There is no further discussion in Chundury of how to determine what is sufficient cross-linking. While, Aoyagi discloses utilizing a prescribed dosage for its single copolymer it does not discuss what energies would be necessary to achieve cross-linking in a polymer blend. Accordingly, based upon a review of these references, there is no likelihood that the radiation dosage levels of Aoyagi would be suitable for the blends of Chundury.

Accordingly, the Examiner has failed to present a *prima facie* case of obviousness, and Applicants respectfully request a withdrawal of this rejection of claims 1-3, 16 and 21-25.

2. *Aoyagi et al. In View of Chundury et al. and Further In View of Barney et al. Do Not Render Claims 38-41 Obvious.*

Claims 38-41 stand rejected under 35 U.S.C. §103(a) as unpatentable in light of Aoyagi et al. in view of Chundury et al and further in view of Barney et al. Because Barney et al. fails to remedy the deficiencies of the combination of Aoyagi and Chundury, the Examiner again has failed to present a *prima facie* case of obviousness for the reasons set forth above regarding this combination. Accordingly, Applicants submit that claims 38-41 are patentably distinguishable over this combination of references.

3 *Aoyagi et al. In View of Chundury et al. and Further In View of Occhiello et al. Do Not Render Claim 23 Obvious.*

Claim 23 stands rejected under 35 U.S.C. §103(a) as unpatentable in light of Aoyagi et al. in view of Chundury et al and further in view of Occhiello et al. Again, because Occhiello fails to remedy the deficiencies of the combination of Aoyagi and Chundury, the Examiner has failed to present a *prima facie* case of obviousness for the reasons set forth above. Accordingly, Applicants submit that claims 23 is patentably distinguishable over this combination of references.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that all pending claims are in a condition for allowance and respectfully requests a notice of the same.

Respectfully submitted,
BELL, BOYD & LLOYD LLC

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BY Joseph Fuchs
Joseph A. Fuchs, Reg. No. 34,604
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4335



Version with Markings to Show Changes Made

1. (Once Amended) A flowable materials container comprising:

a first sidewall and a second sidewall sealed together along a peripheral seam to define a fluid chamber, at least one of the first and second sidewall is a film having at least one layer of ~~a~~ blend of ~~a~~ first component selected from the group consisting of: (1) ethylene and α -olefin copolymers having a density of less than about 0.915 g/cc, (2) ethylene copolymerized with lower alkyl acrylates, (3) ethylene copolymerized with lower alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend, a second component in an amount by weight of the blend from about 45% to about 1% and [consists of one or more polymers of] is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers; and,

D-11 1/2 the film has a modulus of elasticity when measured in accordance with ASTM D882 of less than about 60,000 psi, an internal haze when measured in accordance with ASTM D1003 of less than about 25%, an internal adhesion ranking of greater than about 2, a sample creep at 120°C under 27 psi loading of less than or equal to 150% for a film having a thickness of from about 5 mils to about 15 mils, and the film can be heat sealed into a container having seals wherein the seals remain intact when the container is autoclaved at 121°C for one hour.

2. (Once Amended) The container of claim 1 wherein the second component is a propylene containing polymer and is selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α -olefins having from about 2 to about 17 carbons.

9. (Once Amended) The container of claim 1 wherein the second component is a cyclic olefin [has] having from 5 to about 10 carbons in the ring.

11. (Once Amended) The container of claim 1 wherein the second component is a bridged polycyclic hydrocarbon [has] having at least 7 carbons.

13. (Once Amended) The container of claim 1 wherein the first component is an ethylene and α-olefin copolymer wherein the α-olefin has from 3 to 17 carbons.

14. (Once Amended) The container of claim 1 wherein the first component is an ethylene and α-olefin copolymer wherein the α-olefin has from 4 to 8 carbons.

21. A flowable materials container comprising:

a first sidewall and a second sidewall sealed together along a peripheral seam to define a fluid chamber, the sidewall being of a film having at least one layer of a blend of a first component selected from the group consisting of: (1) ethylene and α-olefin copolymers having a density of less than about 0.915 g/cc, (2) ethylene copolymerized with lower alkyl acrylates, (3) ethylene copolymerized with lower alkyl substituted alkyl acrylates and (4) ionomers, the first component being present in an amount from about 99% to about 55% by weight of the blend;

a second component in an amount by weight of the blend from about 45% to about 1% and [consists of one or more polymers of] is selected from the group consisting of: (1) propylene containing polymers, (2) polybutene polymers, (3) polymethylpentene polymers, (4) cyclic olefin containing polymers and (5) bridged polycyclic hydrocarbon containing polymers; and,

wherein the film is subjected to electron beam radiation [in] having an energy from 150 Kev to 10Kev to provide a dosage amount from about 20 kGy to about 200 kGy.

24. (Once amended) The container of claim 21 wherein the second component is a propylene containing polymer [is] selected from the group consisting of homopolymers of polypropylene, and random and block copolymers and random and block terpolymers of propylene with one or more comonomers selected from α-olefins having from about 2 to about 17 carbons.

31. (Once amended) The container of claim 21 wherein the second component is a cyclic olefin [has] having from 5 to about 10 carbons in the ring.

33. (Once amended) The container of claim 21 wherein the second component is a bridged [poly cyclic] polycyclic hydrocarbon [has] having at least 7 carbons.

35. (Once amended) The container of claim 21 wherein the first component is an α-olefin [has] having from 3 to 17 carbons.

36. (Once amended) The container of claim 21 wherein the first component is an ethylene and α-olefin copolymer wherein the α-olefin has from 4 to 8 carbons.